



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/463,890	04/28/00	KOSZINOWSKI	U 203640

HM12/1002

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EXAMINER

LEFFERS JR, G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/463,890

Applicant(s)

KOSZINOWSKI ET AL.

Examiner

Gerald Leffers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/25/01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of Preliminary Claim (PTO-312)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of applicants' amendment, filed 7/25/01 as Paper No. 9, in which a new paper copy of the sequence listing, corresponding CRF and attorney's statement. These documents have been entered into the file.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc. In the instant case the term "said" is present in the abstract.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36 and 57 are vague and indefinite in that the metes and bounds of the phrase "...a cloning vehicle sequence.....derived from a bacterial artificial chromosome (BAC) and that

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can be replicated in a host cell..." are unclear. It is unclear the nature and number of steps required in order to make a "derivative" of a bacterial artificial chromosome (BAC) in the context of the instant invention. Also, it is unclear what would constitute a "cloning vehicle sequence" in the context of a bacterial artificial chromosome. Does the phrase encompass any nucleotide sequence present in a BAC? Does the term necessarily confer some functional characteristic upon the recombinant vector of the invention, and if so, what characteristic? Moreover, it is unclear as the claim is written whether it is the cloning vehicle sequence or the recombinant vector which must be capable of replication in a host cell and in which cell type (e.g. a eukaryotic or prokaryotic host cell). It would be remedial to amend the claim language to more clearly indicate the limitations intended by the cited phrase.

Claim 45 is vague and indefinite in that the metes and bounds of the phrase "...wherein said cloning vehicle sequence is flanked by identical sequence sections that enable excision of the cloning vehicle..." are unclear. It is unclear as to what sequences the two flanking sequences are intended to be identical. Are the two flanking sequences intended to be identical to one another or to sequences on another vector such that the internal sequences can be exchanged (see for example Figure 19)? It would be remedial to amend the claim language to more clearly indicate what is intended by the term "identical" in context of the claimed invention.

Claims 46, 48-50 are vague and indefinite in that the term "and/or" renders the combination of limitations indefinite. For example, in claim 46, the term "and/or" makes it indefinite whether the limitations include examples wherein there is a combination of a single sequence-specific recombinase and single unique restriction site flanking the cloning vehicle sequence. Upon reading the specification, it appears the use of the term "and/or" is meant to

specify "limitation A or limitation B, or both". It would be remedial to replace the term "and/or" with something like "limitation A or limitation B, or both".

Claim 67 is vague and indefinite in that the metes and bounds of the phrase "...introducing the recombinant vector of claim 36 into a bacterial host cell, which contains DNA molecules..." are unclear. The phrase is unclear in that it appears to add nothing to the base claim in that a bacterial host cell would be expected to comprise DNA molecules. On the other hand, upon reading the specification it is evidence that the "DNA molecules" play a role in the operation of the claimed method in that the DNA molecule is a substrate for homologous recombination with the recombinant vector or that the DNA molecule is otherwise capable of mutating the viral nucleic acid sequence (i.e. a transposon). It would be remedial to amend the claim language to more clearly indicate the relationship of the "DNA molecules" to the recombinant vector in practicing the claimed method for mutagenizing the recombinant vector.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36-40, 42-43 and 51 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Messerle et al (Journal of Molecular Medicine, Vol. 74, No. 4, p.B8, 1996; see the entire reference).

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Messerle et al describe the construction of two BAC/MCMV hybrids wherein the hybrid vectors comprise BAC sequences and an infectious viral genomic sequence >200 kb (i.e. 235 kb minus 15 kb), wherein the hybrid vector can be replicated in E. coli and wherein the vectors can be used to produce MCMV virions (i.e. complementation between the two vectors upon co-transformation in eukaryotic host cells.

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Leffers, Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Rob Schwartzman, Ph.D., can be reached at (703) 308-7307.

Any inquiry of a general nature or relating to the status of this application, or relating to attachments to this office action, should be directed to the Patent Analyst Zeta Adams, whose telephone number is (703) 305-3291.

ADD
G. Leffers Jr., Ph.D.
Patent Examiner
Art Unit 1636
September 30, 2001

David G. G. G.
DAVID G. G. G.
PRIMARY EXAMINER